

REMARKS

Claims 18, 20, 61, 62 and 67-69 are cancelled herein without prejudice or disclaimer and Applicant reserves the right to claim subject matter of the cancelled claims in one or more continuing patent applications. Claims 1, 6-8 and 53-55 are amended herein and claims 71-74 are new. Basis for the amendments and the newly claimed subject matter is in the claims as originally filed and in specification throughout. Representative basis for chromosome positions is in paragraphs 0276 and 0278 of the specification, for example. Accordingly, entry of the claim amendments and new claims will not introduce any prohibited new matter.

The Office rejected claims in the outstanding action for alleged lack of clarity, alleged lack of written description and alleged lack of enablement, which are summarized hereafter:

- i. Claims 55 and 67-69 were rejected under 35 U.S.C. 112, second paragraph, for alleged lack of clarity;
- ii. Claims 1, 2, 6-8, 18-20, 53-55, 61-62 and 67-69 were rejected under 35 U.S.C. 112, first paragraph, for the specification allegedly lacking a written description; and
- iii. Claims 1, 2, 6-8, 18-20, 53-55, 61-62 and 67-69 were rejected under 35 U.S.C. 112, first paragraph, for the specification allegedly lacking an enabling disclosure.

Claim rejections in the outstanding Office action are traversed and are moot in view of the amendments herein. Applicant does not necessarily accept or agree with rejections set forth in the Office action, and the claim amendments, claim cancellations and new claims are submitted herein for the purpose of expediting prosecution. Remarks in response to the outstanding claim rejections and objections are set forth hereafter.

Restriction and Election

Applicant notes the elected polymorphic position, position 36424 in SEQ ID NO: 2, corresponds to chromosome position 87342924 in the pending claims. Claims 1, 6, 8, 19, 53-57 and 73 are generic to the elected subject matter. Applicant notes the Office's position with respect to claims 56 and 57, and these claims are designated "withdrawn" in the complete listing of the claims herein.

Information Disclosure Statement

Applicant will address the Office's comments regarding the information disclosure statement under separate cover.

Objections to the Specification

The Office objected to the specification as it allegedly contained embedded hyperlinks. Text containing the term "www" has been replaced in the specification with "World Wide Web" to remove terms that might be interpreted as embedded hyperlinks.

Claim Objections

The Office objected to claims 18, 54, 62 and 69. Claims 18, 62 and 69 are cancelled herein without prejudice or disclaimer. The duplicative "wherein" clause has been removed from claim 54 and the claim no longer depends from claim 6.

Rejection for Alleged Lack of Clarity

The Office rejected claims 55 and 67-69 under 35 U.S.C. 112, second paragraph, as they allegedly lacked clarity. The rejection is traversed and is rendered moot by the amendments to claim 55 and the cancellation of claims 67-69 herein. Amended claim 55 no longer includes the term "e.g.," and therefore is clear. Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. 112, second paragraph.

Rejection for Alleged Lack of Written Description

The Office rejected claims 1, 2, 6-8, 18-20, 53-55, 61-62 and 67-69 for the specification allegedly lacking a written description of the claimed subject matter. Applicant respectfully notes the rejection is inapplicable to claims 18, 20, 61, 62 and 67-69 as they are cancelled herein without prejudice or disclaimer. The rejection is inapplicable to amended claims 1, 6-8 and 53-55 and the remaining claims, and the rejection is traversed in view of the reasoning presented hereafter.

Well-accepted principles of genetics support a finding that Applicant's specification provided a written description of the claimed subject matter at the time of filing. The concept of linkage disequilibrium in genetics embodies the phenomenon that a disease-associated region in the human genome contains a cluster of polymorphisms associated with a disease state. Specifically,

markers very close to the disease gene will tend, more likely than average, to retain the haplotype of the original chromosome because, as the distance to the disease gene shrinks, it becomes less likely that recombination events will have occurred in this particular region.

From Cantor & Smith, *Genomics: The Science and Technology Behind the Human Genome Project*, 1999, John Wiley & Sons, Inc., New York, page 192. Thus, identifying multiple polymorphisms associated with a disease state within a region also identifies the region as associated with the disease state consistent with the concept of linkage disequilibrium.

The specification analyzed several polymorphisms in the region of the human genome specified by claims 1 and 53 – chromosome positions 87306691 to 87382807 according to Build 33 of the GenBank database – and identified several associated with breast cancer. For example, please see Table 19 on pages 96 to 97 of the specification, which identifies sixteen (16) polymorphisms associated with breast cancer with a p-value of less than 0.05 of the sixty-three (63) polymorphisms analyzed in the claimed region. These associated polymorphisms also are clearly identified in Figure 15 across

the region specified in claims 1 and 53. Thus, the specification provided a written description for the claimed subject matter because Applicant identified a region associated with breast cancer by virtue of identifying several polymorphisms associated with breast cancer in that region.

Applicant therefore respectfully asserts it analyzed a representative number of polymorphic positions in the claimed region. Applicant further identified a representative number of polymorphic variants associated with breast cancer in the region. Accordingly, the specification provides a written description of the claimed subject matter consistent with 35 U.S.C. 112, first paragraph, and withdrawal of the rejection respectfully is requested.

Rejection for Alleged Lack of Enablement

The Office rejected claims 1, 2, 6-8, 18-20, 53-55, 61-62 and 67-69 for the specification allegedly lacking an enabling disclosure of the claimed subject matter. Applicant respectfully notes the rejection is inapplicable to claims 18, 20, 61, 62 and 67-69 as they are cancelled herein without prejudice or disclaimer. The rejection also is inapplicable to amended claims 1, 6-8 and 53-55 and the remaining claims, and the rejection is traversed in view of the reasoning presented hereafter.

Applicant's specification identifies a region specified in claims 1 and 53 associated with occurrence of breast cancer. Given the discussion regarding genetics principles above, Applicant's finding paves the way towards identifying and using polymorphisms of this region in the claimed methods. Applicant's finding that the region specified in claims 1 and 53 is associated with breast cancer guides the person of ordinary skill in the art towards routinely identifying any other polymorphisms associated with breast cancer in that region. The routine nature of any experimentation extending beyond the results described in Applicant's specification is underscored by the clear teachings and guidance in the specification, as elucidated hereafter.

The specification provides multiple working examples in support of the claimed subject matter, an *Ex Parte Foreman* factor bearing on enablement addressed in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). For example,

(i) paragraphs 0245 to 0261 describe methodology for identifying polymorphisms associated with breast cancer in DNA from a human subject;

(ii) paragraphs 0279 to 0281 describe methods and components for identifying polymorphisms associated with breast cancer in DNA from a subject in the region specified by claims 1 and 53; and

(iii) paragraphs 0241 to 0242 describe methods for isolating DNA from human blood samples.

In addition to this set of working examples for performing the claimed methods, the specification also provides clear guidance to the person of ordinary skill in the art for the scope of the claimed subject matter, another factor addressed in *In re Wands* (supra). For example, the specification in paragraphs 0124 to 0128 provides clear guidance for performing multiple types of methods useful for identifying polymorphisms associated with breast cancer.

The Court of Appeals for the Federal Circuit (CAFC) has found some experimentation is acceptable to produce an invention, and routine experimentation does not preclude a finding of enablement (*e.g.*, *Monsanto Co. v. Scruggs*, 459 F.3d 1328; 79 USPQ.2d 1813 (Fed. Cir. 2006) and *In re Wands* (supra)). Given that the working examples and clear guidance in the specification teach multiple methods for identifying polymorphisms associated with breast cancer, the person of ordinary skill in the art could apply these methods in a routine manner to polymorphisms in the region specified by claims 1 and 53 and perform the claimed methods.

The facts and reasoning on which the CAFC found enablement in *In re Wands* are applicable to the same finding of enablement here. In the *Wands* case, the Office erred in rejecting the Applicant's claim to immunoassay methods using a specified generic class of antibodies. The Applicant made a public deposit of a hybridoma cell line that secreted only a specific antibody, yet the CAFC found those skilled in the monoclonal antibody art could, using the state of the art and Applicant's written disclosure, produce and screen other hybridomas secreting other monoclonal antibodies falling within the generic class without undue experimentation.

The technology in *Wands* is similar to the technology described in the present specification in that the person of ordinary skill in the art is prepared to screen additional polymorphisms in the region specified by claims 1 and 53. The specification has disclosed a region of the human genome associated with breast cancer, and the person of ordinary skill in the art now (i) is guided to that region, and (ii) is motivated to routinely identify any other polymorphisms in the region associated with breast cancer, should they exist. Further, multiple screening methods are well-known in the art, as described above, and suited to automated screening platforms. Thus, the rationale in *In re Wands* is applicable to a finding of enablement here.

These factors, coupled with the high level of skill in the art for technology pertaining to the pending claims, leads to the conclusion that any experimentation associated with the full claim scope is routine and not undue. Accordingly, the specification provides an enabling disclosure of the claimed subject matter consistent with 35 U.S.C. 112, first paragraph. Applicant therefore respectfully requests withdrawal of the rejection.

CONCLUSIONS

Applicant respectfully submits all pending claims will be in condition for allowance upon entry of the amendments herein. Applicant respectfully solicits a prompt notification to this effect, and the Examiner is encouraged to contact the undersigned representative (contact information below) to promptly resolve any remaining issues or questions.

In the unlikely event a relevant document is separated from this Amendment and the Office determines that an extension and/or other relief is required, Applicant petitions for any required relief, including extensions of time, and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-3473**.

Respectfully submitted,

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